Individual Safety Report

3204261-6-00-01

Form Approved: OMB No. 0910-0291

FDA Use Only

Triage unit sequence # 98039

MEDWATCH

for VOLUNTARY reporting by health professionals of adverse events and product problems

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1 CDER CDER

A. PATIENT INFORMATION

1. Patient identifier	2. Age at event	3. Sex	4. Weight
[redacted]	72 or DOB: [redacted]	[ ] female [X] male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product problem

2. Outcomes attrib. to event
[ ] death (mo/day/yy)
[ ] life-threatening
[X] hospitalization - initial or prolonged
[ ] disability
[ ] congen anomaly
[ ] required intervention to prevent perm impair/damage
[ ] other:

3. Date of event 10/03/1998

4. Date of this Rept 10/03/1998

5. Describe event or problem

72 y/o WM with PMH bladder carcinoma s/p cystectomy presented to the ED with a 5 day history of productive cough, fever, malaise, and myalgias. For his symptoms, he had been consuming numerous acetaminophen tablets as well as cold preparations containing acetaminophen. The patient also reported consumption of 6-12 cans of beer daily. In the ED, he was found to be afebrile, with mild labored breathing. On exam, his liver was enlarged, and labs revealed an AST 1456, ALT 620, Alk Phos 256. The patient was admitted with presumed pneumonia and hepatitis secondary to EtOH and APAP use. Blood toxicology revealed and APAP level = 12, and a salicylate level <20. He was admitted to the MICU and treated with 17 doses of N-Acetylcysteine, as there was concern of chronic toxicity. He received antibiotic therapy for his pneumonia and symptoms improved. At time of discharge 10/8, LFT's were decreased, Alk Phos 203, AST 105, ALT 171. Follow-up visits with patient indicate he has decreased his EtOH consumption and LFT's on 11/3/98 were further decreased, Alk Phos 127, AST 28, ALT 30.

6. Relevant tests/laboratory data, including dates

RECD.

FEB 2 3 '99

MEDWATCH CTU

7. Other relevant history, including preexist. med. conditions

C. SUSPECT MEDICATION(S)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Acetaminophen
#

2. Dose, frequency & route
#1
#

3. Therapy dates(if unk, give dur)
#1
#

4. Diagnosis for use (indication)
#1
#

5. Event abated after use stopped or dose reduced
#1 [X]yes [ ]no [ ]N/A
[ ]yes [ ]no [ ]N/A

6. Lot # (if known)
#1
#

7. Exp. Date
#1
#

8. Event reappeared after reintroduction
#1 [ ]yes [ ]no [X]N/A
[ ]yes [ ]no [ ]N/A

9. NDC # for prod problems only
#1
#

10. Concomitant medical products and therapy dates

D. SUSPECT MEDICAL DEVICE

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of Dev.
[ ] Hlth Profes.
[ ] lay user/pat.
[ ] other:

5. Expiration Date

6. Model# _____
catalog# _____
serial# _____
lot# _____
other# _____

7. If implanted, give date

8. If removed, give date

9. Device available for evaluation? (Do not send to FDA)
[ ] yes [ ] no [ ] returned to mfr on

10. Concomitant medical products and therapy dates

E. INITIAL REPORTER

1. Name, address & phone #

Michael Sutherland, Pharm.D.
VA Medical Center
3200 Vine Street
Cincinnati, OH 45220
Phone: (513) 861-3100

2. Health profess.? [X] yes [ ] no

3. Occupation Pharmacist

4. Also reported to
[ ] manufacturer
[ ] user facility
[ ] distributor

5. If you do NOT want your identity disclosed to the Mfr, place an 'X' in box [ ]

MED INFO ASSOC Facsimile Form 3500 Mail to: MedWatch 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 98039